



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 09/734,801 | 12/12/2000 | Roland Carlsson | EricPotter | 5194 |
| 110 | 7590 | 01/27/2004 | EXAMINER | |
| DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307 | | | CHUNDURU, SURYAPRABHA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1637 | |

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,801

Applicant(s)

CARLSSON ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action filed on December 29, 2003 has been entered and considered.
2. The Terminal Disclaimer filed on December 29, 2003 has been entered and considered.
3. The instant application is filed on December 12, 2000, which claims no priority date.
4. Claims 1-7 are pending.

Response to arguments

5. Applicants' response to the office action is fully considered and found persuasive.
6. With reference to the rejection made in the previous office action under 35 USC 112, second paragraph applicants' arguments are fully considered and the rejection is withdrawn in view of the amendment.
7. With reference to the rejections made in the previous office action under obviousness-type double patenting, terminal disclaimer is considered and the rejections are withdrawn in view of the terminal disclaimer.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al.

(Gene, Vol. 243, pp. 133-137, 2000) in view of Stemmer et al. (USPN. 6,413,774).

Kikuchi et al. teach a method of claim 1, for generating a polynucleotide sequence or a population of sequences from parent single stranded polynucleotide sequences encoding one or more protein motifs, wherein Kikuchi et al. discloses that the method comprises (a) providing single stranded polynucleotide sequences consisting of plus and minus strands (complementary strands) of parent polynucleotide sequences wherein each of the complementary single strands (plus and minus) were derived from two separate parent single stranded polynucleotide containing plasmid vectors (SK-nahH and KS-xylE plasmids) and said first population (SK-nahH) generated from plus strands being separate from said second population (KS-xylE) generated from minus strands (see page 134, column 1, paragraph 2.3, page 135, Fig.1); (b) digesting each single stranded polynucleotide sequences with an endonuclease (DNAse) to generate a first population of single stranded fragments (plus strands) and a second population of single strand fragments (minus strands) (see page 134, column 1, paragraph 2.3, page 135, Fig. 1, page 136, column 1, paragraph 1); (c) contacting said first and second population of single stranded fragments to anneal with each other (see page 134, paragraphs 2.2 - 2.3, page 135, Fig. 1); and (d) amplifying the annealed fragments to generate a polynucleotide sequence encoding one or more protein motifs having altered characteristics compared to said parent polynucleotides (see page (see page 134, paragraphs 2.2 - 2.3). However, Kikuchi et al. did not teach use of an exonuclease to digest the single-stranded polynucleotides.

Stemmer et al. teach a method of claims 1, 3, 7, for generating polynucleotides having desired characteristics, wherein Stemmer et al. disclose use of exonucleases such as BAL31, Bacteriophage Lambda exonuclease, E.coli. exonuclease I, III, and VII (see column 49, lines 65-67, column 50, lines 1-12). With regard to claim 7, Stemmer et al. also teach that the method

Art Unit: 1637

comprises contacting polynucleotide sequence of step (d) of claim 1, with primer sequences that anneal to 3' and 5' ends of at least one of the parent polynucleotides under annealing conditions and amplifying those hybrids (see column 11, lines 10-25); With regard to claims 4-6, Stemmer et al. teach that the method comprises mutagenizing parent polynucleotides by error-prone PCR (see column 26, lines 62-67).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of generating a polynucleotide sequence encoding one or more protein motifs as taught by Kikuchi et al. with the use of exonuclease digestion and amplification using primer sequences for generating polynucleotides having desired characteristics as taught by Stemmer et al. to achieve expected advantage of developing a sensitive method for generating a polynucleotide sequence(s) encoding one or more protein motifs having altered characteristics because Stemmer et al. taught that "exonuclease removes non-templated nucleotides from the polynucleotides and amplification using primers annealing to polynucleotides would remove non-shuffled polynucleotide products (see column improved shuffling of polynucleotides (see column 49, lines 65-67, column 50, lines 1-7, column 11, lines 14-25). An ordinary practitioner would have been motivated to combine the method of Kikuchi et al. with the limitations taught by Stemmer et al. to enhance the sensitivity and specificity of the assay by incorporating the exonuclease digestion and PCR amplification with primers because these limitations would remove non-template products and non-shuffled products and improve the specificity of the method to obtain an altered polynucleotide sequence(s) with highly desirable characteristics.

Art Unit: 1637


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
January 13, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER